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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,378	11/23/2004	Georg Lutter	ROS-101	6218
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HOLLANDER LAW FIRM, P.L.C. SUITE 305 10300 EATON PLACE FAIRFAX, VA 22030			MEHTA, BHISMA	
			ART UNIT	PAPER NUMBER
			3767	

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/510,378

**Applicant(s)**

LUTTER, GEORG

**Examiner**

Bhisma Mehta

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 October 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/5/2004</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. Part of the information disclosure statement filed October 5 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The references, which have been crossed out by the examiner, have not been considered.

### ***Drawings***

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the passage being provided with a sluice mechanism by means of which the passage is sealed fluid-tight in an inflated state (claim 1) and the passage being bound sickle-like by the circumferential edge of the dilation unit and the remaining part of the aortic wall (claim 3) must be shown or the feature(s) canceled from the claim(s). Also, the passage being completely surrounded by the dilation unit of claim 4, the pump device of claim 7 and the coronary artery perfusion catheters with cuffs of claim 14 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures

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appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to because Figure 1 does not clearly show the components of the perfusion catheter arrangement, i.e., the catheters and dilation units are not clearly drawn. Also, the perfusion catheter labeled "C" is not shown clearly as it is not clear if the sluice element (11) is a part of the perfusion catheter "C" or a separate instrument. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement

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sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Reference character AD is shown in Figure 3 but is not described in the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification***

5. The abstract of the disclosure is objected to because it is too long and it contains legal phraseology. Also, there is a grammatical error in line 7 in the phrase "in an inflated state an at". Correction is required. See MPEP § 608.01(b).

6. The disclosure is objected to because of the following informalities: In line 23 of page 5, there is a grammatical error in the phrase "in an inflated state an at". Appropriate correction is required.

***Claim Objections***

7. Claims 1–13 are objected to because of the following informalities: In line 6 of claim 1, there is a grammatical error in the phrase "in an inflated state an at". Appropriate correction is required. In claim 5, the use of "on the one hand" and "on the other hand" is confusing with respect to the location of the passage and the ring-shaped sluice.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 1-13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one

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skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In claim 1, it is unclear what is being claimed in reference to the sluice element and how the sluice mechanism can allow the passage to be sealed fluid-tight in an inflated state. In claim 3, it is unclear what is being claimed with regards to the passage being bound sickle-like by the circumferential edge of the dilation unit and the remaining part of the aortic wall.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In line 12 of claim 1, it is unclear what the phrase "in an inflated state" is referring to, i.e., the sluice mechanism or the dilation unit. In claim 5, it is unclear if the "ring-shaped sluice" is in addition to the sluice mechanism of claim 1 or a different component. In claim 10, it is unclear what is meant by the "opposite channel wall regions".

### ***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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13. Claims 1- 5, 7, and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by St. Goar et al (U.S. Patent No. 6,090,096). In Figures 8 and 10, St. Goar et al disclose a perfusion catheter (80) designed as a hollow channel or shaft and dilation units or inflatable balloon elements (84 and 110). A passage (86, 92, or 98) is provided which projects through the dilation unit (110) and is sealed fluid-tight with respect to the dilation unit in an inflated state. The passage is surrounded by the perfusion catheter and by the dilation unit. As to claim 2, in lines 19-34 of column 11, St. Goar et al teach that the dilation units are disposed at a distance of at least 1 cm from each other. As to claim 3, the passages are provided at a circumferential edge of the dilation unit, i.e., the edge of the dilation unit through which the passages project and at least one passage is bound sickle-like by the circumferential edge of the dilation unit and the remaining part of the aortic wall. As to claim 7, openings (102 and 100) are provide and, in lines 19-23 of column 8 and lines 50-54 of column 11, St. Goar et al teach providing a pump or pressurized fluid source (59). As to claim 9, a working channel (92) is provided with an opening (96). As to claim 11, the dilation elements are connected to a supply line through which a fluid source is introduced for inflating.

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to



be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over St. Goar et al in view of Valley et al (U.S. Patent No. 5,814,016). St. Goar et al disclose the invention substantially as claimed. However, St. Goar et al are silent on the proximal dilation unit being disposed in a rotary manner about the perfusion catheter. In Figure 29, Valley et al show a catheter having proximal and distal dilation units and, in lines 10-55 of column 26, teach that the dilation unit can be rotated about the catheter to collapse the dilation unit to its lowest possible deflated profile when the catheter is introduced or withdrawn through a peripheral arterial access site. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter of St. Goar et al to allow the dilation unit to be rotated about the catheter as taught by Valley et al as both St. Goar et al and Valley et al teach using the catheters within the arteries of a patient's heart and it is desirable to have the dilation unit in the lowest possible deflated profile when the catheter is being advanced through the narrow passageways of a patient's body.

16. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over St. Goar et al in view of Kong (Publication No. U.S. 2002/0120234). St. Goar et al disclose the invention substantially as claimed. However, St. Goar et al are silent on the dilation units being designed as suction elements and having a bell-shaped form with a suction line. In Figure 1, Kong shows a catheter where the dilation unit or balloon is designed as a suction element and has a bell-shaped

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form and teaches using a suction line to allow the balloon to maintain a fluid-tight seal to a wall of a blood vessel. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dilation units of St. Goar et al to be a suction element with a bell-shaped form and a suction line as taught by Kong as both St. Goar et al and Kong teach that it is desirable for the dilation units to maintain a fluid-tight seal at the location in a patient's body where a surgical procedure is being performed.

17. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over St. Goar et al and Kong as applied to claim 12 above, and further in view of Wang et al (U.S. Patent No. 5,195,969). St. Goar et al and Kong disclose the invention substantially as claimed. St. Goar et al disclose the dilation units as being made of an elastic material and enclosing an inflatable volume. However, both St. Goar et al and Kong are silent on the dilation units being double-walled. Wang et al disclose a catheter having a double-walled dilation unit. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the elastic dilation unit of St. Goar et al double-walled as taught by Wang et al as Wang et al teach that a double-walled dilation unit provides strength to the dilation unit so that it can be inflated safely and this is highly desirable when inflating dilation units in locations in a patient's body where a surgical procedure is being performed.

18. Claims 8, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over St. Goar et al in view of Boyd et al (U.S. Patent No. 5,738,652). St. Goar et al discloses introducing coronary artery catheters (69

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and 71) into the coronary arteries and inflating a cuff (75) which allows a blood flow to be ensured through the catheters into the coronary arteries. Furthermore, in lines 16-19 of column 8, St. Goar et al teach that other components and features of cardiopulmonary bypass systems may be used that would be apparent to those of skill in the art. St. Goar et al teach positioning the perfusion catheter inside the aorta so that the aortic valve is surrounded by the dilation units and inflating the dilation units so that the units are located close to the aortic wall in a fluid-tight manner. St. Goar et al also teach visualizing the aorta. St. Goar et al disclose the invention substantially as claimed. However, St. Goar et al do not teach emptying the blood volume between the two dilation units by means of an auxiliary catheter projecting through the proximal dilation unit, separating the aortic valve by means of a separation instrument projecting through the proximal dilation unit, and conducting the separating under optical observation by means of an optic catheter where multiple passages or catheters are provided projecting through a dilation unit. In line 54 of column 12 to line 32 of column 13, Boyd et al teach using a cardiopulmonary bypass system and a catheter where a working volume is created between a dilation unit (11) and the aortic valve by removing the fluid within that area by introducing multiple catheters which project through the dilation unit. Boyd et al also teach using a cutter to separate the aortic valve and using an angioscope to observe the separation of the aortic valve. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the catheter of St. Goar et al with multiple auxiliary catheters as taught by Boyd et al Boyd et al

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teach that it is well known to use auxiliary catheters projecting through a dilation unit for creating a working volume, for separating the aortic valve, and for conducting the separation under optical observation.

### ***Conclusion***

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Don Michael (U.S. Patent No. 5,163,905), Simpson et al (U.S. Patent No. 5,462,529), Afzal (U.S. Patent No. 6,210,365), Buscemi et al (U.S. Patent No. 6,299,597), and Samson et al (U.S. Patent No. 6,673,040) disclose catheters with dilation units.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
BM

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

